

K964893

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**510(K) PREMARKET NOTIFICATION
SUMMARY OF SAFETY AND EFFECTIVENESS
HANSSON PIN™ SYSTEM**

Submission Information

**Name and Address of the Sponsor
of the 510(k) Submission:**

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Date Summary Prepared:

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Device Identification

Proprietary Name:

Hansson Pin™ System

Common Name:

Femoral Neck Fracture Fixation Device

Classification Name and Reference:

Smooth or Threaded Metallic Bone Fixation
Fastener
21 CFR §888.3040

Predicate Device Identification

The Hansson Pin™ System is substantially equivalent to other legally marketed, Class II, femoral neck fracture fixation devices. The predicate devices are as follows: Howmedica Knowles Hip Pins (preamendment device), Zimmer Knowles Hip Pins (preamendment device), and Howmedica Gouffon Hip Pin System (K760454).

Device Description

The Hansson Pin™ System is a femoral neck fracture fixation device. Each pin consists of two parts: an outer sleeve and an inner sliding tongue, and is provided pre-assembled. The outer sleeve features a proximal window, where the inner sliding tongue's hook protrudes when properly introduced. Two pins are inserted into parallel drill holes through the femoral neck and into the femoral head. Fixation of the pin in the femoral head is achieved when the inner sliding tongue is intraoperatively pushed up partially through the proximal window, and the end hook curls around into the subchondral bone. The pins measure 6.5mm in diameter, are available in lengths ranging from 80mm to 150mm, and are made of ASTM F-138 Stainless Steel 316 LVM.

Intended Use

The Hansson Pin™ System is intended for the treatment of reducible intracapsular femoral neck fractures, i.e. subcapital and transcervical fractures, and has been designed to minimize surgical trauma to the patient and offer secure, stable fixation.

Statement of Technological Comparison

The subject device shares the same materials, intended use, and basic surgical preparation and insertion procedures as that of the predicate devices. Though the method of fixation for the subject device differs from that of the predicate devices, testing performed substantiates the use of the subchondral bone end hook design for fixation of the pins.